

55 REQUESTED DOCUMENTS FOR IR3535 TGAI/MP

44270800 Merck KGaA (1997) Series Transmittal of 40 Studies.

Citations:

44270801 Slesinski, R.; Irvine, L.; Phillips, S. et al. (1997) Statutory Findings and Information Summaries: Information Addressing the Food Quality Protection Act (FQPA) of 1996: (IR3535). Unpublished study prepared by Technical Assessment Systems, Inc. 12 p.

44270802 Phillips, S., comp. (1997) (Paragraph) 61 Series Chemistry Information for Insect Repellent 3535 (IR3535), Technical Grade Active Ingredient. Unpublished study prepared by Technical Assessment Systems, Inc. 47 p.

44270803 Brekelmans, M. (1997) Determination of the Purity and Impurities of Insect Repellent 3535 (TGAI): Lab Project Number: 183746: 64008. Unpublished study prepared by NOTOX B.V. 74 p.

44270804 van Rijsbergen, L. (1996) Determination of Appearance of Insect-Repellent 3535 (TGAI): Lab Project Number: 183601: 64008. Unpublished study prepared by NOTOX B.V. 17 p. {OPPTS 830.6302, 830.6303, and 830.6304}.

44270805 van Rijsbergen, L. (1997) Determination of the Boiling Temperature of Insect-Repellent 3535 (TGAI): Lab Project Number: 183612: 64008. Unpublished study prepared by NOTOX B.V. 22 p. {OPPTS 830.7220}.

44270806 van Rijsbergen, L. (1996) Determination of the Density (Liquid) of Insect-Repellent 3535 (TGAI): Lab Project Number: 183623: 64008. Unpublished study prepared by NOTOX B.V. 22 p. {OPPTS 830.7300}.

44270807 van der Baan-Treur, J. (1997) Determination of the Water Solubility of Insect-Repellent 3535 (TGAI): Lab Project Number: 183645: 64008. Unpublished study prepared by NOTOX B.V. 36 p. {OPPTS 830.7840}.

- 44270808 Vogels, M. (1996) Determination of the Solubility of Insect-Repellent 3535 (TGAI) in 6 Organics Solvents: Lab Project Number: 183735: 64008. Unpublished study prepared by NOTOX B.V. 23 p.
- 44270809 van Rijsbergen, L. (1997) Determination of the Vapour Pressure of Insect-Repellent 3535 (TGAI): Lab Project Number: 183634: 64008. Unpublished study prepared by NOTOX B.V. 24 p. {OPPTS 830.7550}.
- 44270810 van der Baan-Treur, J. (1996) Determination of the Partition Coefficient (N-Octanol/Water) of Insect-Repellent 3535 (TGAI): Lab Project Number: 183656: 64008. Unpublished study prepared by NOTOX B.V. 35 p. {OPPTS 830.7570}.
- 44270811 van Rijsbergen, L. (1996) Determination of the pH of an Aqueous Dispersion of Insect-Repellent 3535 (TGAI): Lab Project Number: 183702: 64008. Unpublished study prepared by NOTOX B.V. 23 p. {OPPTS 830.7000}.
- 44270812 van Rijsbergen, L. (1996) Determination of the Low Temperature Stability of Insect-Repellent 3535 (TGAI): Lab Project Number: 183689: 64008. Unpublished study prepared by NOTOX B.V. 22 p. {OPPTS 830.6313}.
- 44270813 van Rijsbergen, L. (1996) Determination of the Accelerated Storage Stability of Insect-Repellent 3535 (TGAI) by Heating: Lab Project Number: 183757: 64008. Unpublished study prepared by NOTOX B.V. 25 p. {OPPTS 830.6313}.
- 44270814 Vogels, M. (1997) Direct Phototransformation of Insect-Repellent 3535 (TGAI) in Water: Lab Project Number: 184433: 64008. Unpublished study prepared by NOTOX B.V. 36 p. {OPPTS 830.6313}.
- 44270815 van der Baan-Treur, J. (1996) Determination of the Stability of Insect-Repellent 3535 (TGAI) to Metals and Metal Ions: Lab Project Number: 183768: 64008. Unpublished study prepared by NOTOX B.V. 28 p. {OPPTS 830.6313}.
- 44270816 van Rijsbergen, L. (1996) Determination of the Flash-Point of Insect-Repellent 3535 (TGAI): Lab Project Number: 183667: 64008. Unpublished study prepared by NOTOX B.V. 23 p. {OPPTS 830.6315}.
- 44270817 van der Baan-Treur, J. (1997) Determination of the Storage Stability of Insect-Repellent 3535 (TGAI) Over 1 Year: Interim Report: Lab Project Number: 183678: 64008. Unpublished study prepared by NOTOX B.V. 24 p. {OPPTS 830.6317}.
- 44270818 van Rijsbergen, L. (1997) Determination of the Viscosity of

Insect-Repellent 3535 (TGAI): Lab Project Number: 183713: 64008. Unpublished study prepared by NOTOX B.V. 23 p. {OPPTS 830.7100}.

- 44270819 van Rijsbergen, L. (1997) Determination of the UV-VIS Absorption Spectra of Insect-Repellent 3535 (TGAI): Lab Project Number: 193332: 64008. Unpublished study prepared by NOTOX B.V. 28 p. {OPPTS 830.7050}.
- 44270820 Heusener, A. (1997) Insect Repellent 3535--Acute Toxicity Study in Rats after Oral Administration: Lab Project Number: T14215. Unpublished study prepared by Institute of Toxicology, Merck KGaA. 25 p.

44270821 Gamer, A.; Leibold, E.; Hoffman, H. (1996) Study on the Acute Inhalation Toxicity LC50 of... (Insekt-Repellent 3535) as a Liquid Aerosol in Rats 4-Hour Exposure: Final Report: Revised: Lab Project Number: 13I0189/957012. Unpublished study prepared by BASF Aktiengesellschaft. 49 p.

44270822 Heusener, A. (1997) Insect Repellent 3535...Primary Eye Irritation Test in Rabbits: Lab Project Number: T13919. Unpublished study prepared by Institute of Toxicology, Merck KGaA. 28 p.

44270823 Phillips, S., comp. (1997) Supplemental Dermal Irritation and Sensitization Information on Rabbits, Guinea Pigs and Humans: (IR 3535). Unpublished study prepared by Technical Assessment Systems, Inc. 24 p.

44270824 Leushner, F.; Leushner, A.; Schwerdtfeger, W. et al. (1974) 4 Week Toxicity of BE 3535 in Sprague-Dawley Rats After Administration in the Diet: Lab project Number: MERCK SC DIET. Unpublished study prepared by Laboratorium fur Pharmakologie und Toxikologie. 102 p.

44270825 Schardein, J. (1997) A Dose Range-Finding Developmental Toxicity Study of IR 3535 in Rabbits: Final Report: Lab Project Number: WIL-149020. Unpublished study prepared by WIL Research Labs., Inc. 213 p.

44270826 Gleich, J. (1996) Insect Repellent 3535... Developmental Toxicity Study with Oral Administration to Rabbits: Final Report: Lab Project Number: T 9382. Unpublished study prepared by Institute of Toxicology, Merck KGaA. 279 p.

44270827 Gleich, J.; Weibe, G.; Hofmann, A. (1997) Insect Repellent 3535...Investigatory Study T 9385 with Oral Administration to Rabbits: Lab Project Number: T9385INV.DOC. Unpublished study prepared by Institute of Toxicology, Merck KGaA. 73 p.

44270828 Gleich, J.; Weibe, G.; Hofmann, A. (1997) Insect Repellent 3535 ...Investigatory Study T 9400 with Oral Administration to Himalayan and New Zealand White Rabbits: Lab Project Number: T9400I-U.DOC: 649225. Unpublished study prepared by Institute of Toxicology, Merck KGaA. 29 p.

44270829 Utesch, D. (1996) Insect Repellent 3535...Bacterial Mutagenicity Assay, Salmonella typhimurium and Escherichia coli: Lab Project Number: IR3535AM.DOC: IR3535TL.DOC: T13942. Unpublished study prepared by Institute of Toxicology, Merck KGaA. 30 p.

44270830 Murli, H. (1996) Mutagenicity Test on IR 3535 Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells with and without Exogenous Metabolic Activation: Final Report: Lab Project Number: 17982-0-437: CY11086: CY9206. Unpublished study prepared by Corning Hazleton Inc. 33 p.

44270831 Marshall, R. (1996) Insect Repellent IR 3535...Induction of Micronuclei in the Bone Marrow of Treated Mice: Final Report: Lab Project Number: 221/12-1052: 221/12. Unpublished study prepared by Corning Hazleton (Europe). 51 p.

44270832 Phillips, S. (1997) Toxicology Summary and U.S. Army Hazard Evaluation: (Insect Repellent 3535). Unpublished study prepared by Technical Assessment Systems and E. Merck. 38 p.

44270833 Arcelin, G.; Stegehuis, D. (1996) Insect Repellent 3535...28-Day Toxicokinetic Study with Dermal Application to Rats: Lab Project Number: 398823: 391792: 395392. Unpublished study prepared by Research and Consulting Co., Ltd. and Biological Research Labs., Ltd. 131 p.

44270834 Burri, R. (1996) (Carbon-14) Insect Repellent 3535...Bioretention Study in Male Rats after Single Dermal Administration of the (carbon-14)-Labelled Compound at a Dose Level of 1.0 MG/CM(2): Lab Project Number: 612966: 900797: 603213. Unpublished study prepared by RCC Umweltchemie AG. 79 p.

44270835 Burri, R. (1996) Insect Repellent 3535...Dermal Absorption and Pharmacokinetic Study on Various Organs and Tissues of Male Rats and Excretion Pattern of Radioactivity after Single Dermal Administration of the (carbon-14)-Labelled Compound: Lab Project Number: 398147: 391792: 384311. Unpublished study prepared by RCC Umweltchemie AG. 158 p.

44270836 Cilek, J. (1996) Laboratory Evaluation for the Efficacy of Merck KGaA, Insect Repellent 3535 against Stable Flies and Deer Ticks: Lab Project Number: IR 3535-FL-95.01. Unpublished study prepared by Florida A & M University. 10 p.

- 44270837 Hunter, F.; Sutcliffe, J. (1995) In vitro Assay to Determine the Efficacy of Merck KGaA, Insect Repellent 3535 against Black Flies, Deer Ticks and Stable Flies: Lab Project Number: IR 3535-CN-95.02. Unpublished study prepared by Brock University and Trent University. 29 p.
- 44270838 Benzon, G. (1997) Results of in vitro Assay of Merck KGaA Insect Repellent 3535 against Nymhal Deer Ticks, Ixodes scapularis: Lab Proj ect Number: IR 3535-PA-95.03. Unpublished study prepared by Benzon Research. 11 p.
- 44270839 Schardein, J. (1997) A Two-Week Repeated Dose Toxicity Study of IR 3535 in Non-Pregnant Rabbits: Final Report: Lab Project Number: WIL-149022: WIL-149021.13: WIL-149021. Unpublished study prepared by WIL Research Labs., Inc. 136 p.
- 44270840 Phillips, S., comp. (1997) Additional Efficacy Studies: (Insect Repellent 3535): Lab Project Number: N0591296003A061: 059-0051-A: 059-0051. Unpublished study prepared by Merck KGaA. 74 p.

44297900 EM Industries, Inc., Transmittal of 8 Studies.

Citations:

- 44297901 Phillips, S., comp. (1997) Supplemental Chemistry Information: (Insect Repellent 3535). Unpublished study prepared by TAS, Inc. 53 p.
- 44297902 Morris, T. (1997) Delayed Contact Hypersensitivity Study in Guinea Pigs (Buehler Technique): IR3535 Technical: Lab Project Number: 96-8304-21. Unpublished study prepared by Hill Top Research Ltd. 41 p.
- 44297903 Pfister, T.; Luetkemeier, H.; Stegehuis, D.; et al. (1996) Insect Repellent 3535....: 90-Day Subchronic Toxicity Study with Dermal Application to Rats: Final Report: Lab Project Number: 398834. Unpublished study prepared by RCC, Research and Consulting Co., Inc.; RCC Pharmanalytics, Ltd.; and BRL, Biological Research Labs, Ltd. 501 p.
- 44297904 Gleich, J. (1997) Insect Repellent 3535....: 2-Generation Study with Oral Administration to Rats: Final Report: Lab Project Number: T 9381. Unpublished study prepared by Merck KGaA. 778 p.

44297905 Oesch, F.; Hengstler, J. (1996) Insect Repellent 3535...: Mammalian Cell (V79) Gene Mutation Test: Lab Project Number: AFP 128. Unpublished study prepared by University of Mainz. 23 p.

44297906 van Dijk, A. (1996) Insect Repellent 3535...: Pharmacokinetics and Metabolism Study after Intravenous and Dermal Applications of the (Carbon 14)-Labelled Compound to Male Rats and Rabbits: (Final Report): Lab Project Number: 392883. Unpublished study prepared by RCC Umweltchemie AG. 138 p.

44297907 Ladstetter, B. (1996) Insect Repellent 3535...: in vitro Metabolism in Hepatocytes of Rat and Man: Lab Project Number: 16/34/95. Unpublished study prepared by Ludwig-Maximilians-Universitaet Muenchen and Merck KGaA. 35 p.

44297908 Phillips, S., comp. (1997) Consumer Information Requested and Received from European Producers Concerning the Use of IR3535 in Formulations. Unpublished study prepared by TAS, Inc. 20 p.

Merck KGaA (1997) Transmittal of 1 Study.

44323301 Schardein, J. (1997) A Development Toxicity Study of IR 3535 in Rabbits: Final Report: Lab Project Number: WIL-149021. Unpublished study prepared by WIL Research Labs., Inc. 347 p.

EM Industries, Inc. (1998) Transmittal of 1 Study.

44482401 Van Helvoirt, J. (1998) Determination of the Storage Stability and Corrosion Characteristics of Insect-Repellent 3535 (TGAI) Over 1 Year: Lab Project Number: 183678: 64008. Unpublished study prepared by NOTOX B.V. 52 p. {OPPTS 830.6317, 830.6320}

EMD Chemicals, Inc. (2004) Transmittal of 3 Studies.

46327101 Utesch, D. (2004) Art. 111887 (Insect Repellent IR 3535) - In Vitro Chromosome Aberration Assay in V79 Chinese Hamster Cells. Project Number: T14376/ART/111887. Unpublished study prepared by E. Merck Institute for Toxicology. 33 p.

46327102 Marshall, R. (1999) Insect Repellent IR 3535 (Art. No. 111887): Induction of Chromosome Aberration in the Bone Marrow of Treated Rats: Final Report. Project Number: 70/76/D5140, 70/76, 728706. Unpublished study prepared by Covance Laboratories, Ltd. and RCC Umweltchemie Ag. 67 p.

46327103 Marshall, R. (1999) Insect Repellent IR 3535 (Art. No. 111887): Collection of Plasma and Bone Marrow Samples from Treated Mice: Final Report. Project Number: 70/71/D5140, 70/71, 721067. Unpublished study prepared by Covance Laboratories, Ltd. and RCC Umweltchemie Ag. 34 p.

EMD Performance Materials Corporation (2015) Transmittal of 1 Study.

49677001 Pintat, J. (2013) Analytical Methods and Data for IR3535(R). Unpublished study prepared by Merck, S.L. 38p.

EMD Performance Materials Corporation (2015) Transmittal of 1 Study.

49790701 Phillips, S. (2015) Analytical Methods & Data for IR3535(R). Project Number: AMR1887/GCREV2. Unpublished study prepared by EMD Performance Materials Corporation. 49p.